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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,940	09/09/2003	Jason D. Meridew	5490-000341	1613
27572	7590	01/20/2006	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C.			SHAFFER, RICHARD R	
P.O. BOX 828			ART UNIT	
BLOOMFIELD HILLS, MI 48303			PAPER NUMBER	

3733

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/657,940	Applicant(s) MERIDEW ET AL.	
	Examiner Richard R. Shaffer	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16-21, 24, 25, 27-31, 35-38 and 40-44 is/are rejected.
- 7) ☒ Claim(s) 9-12, 22, 23, 26 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/5/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election of **Species I (Figure 1)** for the bone screw and **Species I (Figure 8)** for the staple directed to claims 1-12, 16-38, and 40-43 in the reply filed on December 13th, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Examiner agrees with applicant, but wishes to clarify that because applicant has stated the remaining claims are directed to the elected species, that linearly driving a screw and threading/rotating a screw (claims 26, 27, 31, 32, 38, and 42) are the same thing. If one threads a screw into place, they are in effect linearly driving it into place.

Claims 13-15 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 13th, 2005.

Claim Objections

Claims 42 and 42 are objected to because of the following informalities: Applicant has submitted two different claims numbered 42. The correct numbering should be 42, 43, and 44. For examination purposes, the second claim 42 has been treated as claim 44. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim currently positively recites being connected to the human body by the phrase "the implant is coupled within an aperture defined by a bone." It is recommended to simply change "coupled" to "adapted to be coupled" in order to avoid positively claiming the human body. For examination purposes, the claim has been interpreted according to the examiner's recommendation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 16-21, 24, 25, 27-29, 35, 36, 38, and 40-44 rejected under 35 U.S.C. 102(b) as being anticipated by Kohrs, et al (US Patent 5,897,593).

[First Interpretation] In regard to claims 1-6, 8, 36, 38, and 40-44, Kohrs, et al discloses a system comprising: a generally cylindrical threaded bone screw (Figure 1) with two channels (44a) extending from a first end (24) to the second end (22) having an anchor locking surface (44); a driver (Figure 14) having a threaded cutting portion (114) and a driving portion (112a); wherein the cutting portion is configured to form an implant engaging surface within bone; and wherein the driving portion is configured to drive the implant into engagement with the implant engaging surface.

In Column 7, Line 55 through Column 8, Line 65, the surgical method pertinent to the claimed limitations are disclosed. A method of forming an aperture within a bone; coupling the implant to a driver (Figure 14), rotating the implant causes the implant to

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linearly translate into the aperture while simultaneously having the driver and implant form a threaded implant engaging surface within the aperture.

[Second Interpretation] In regard to claims 16-21, 24, 25, 27-29, and 35, Kohrs, et al discloses an generally cylindrical implant (Figure 1) having a first end (24), a second end (22), a threaded outer surface, and two channels (44a); a staple (Figure 14) having a locking surface (116b) to engage with the surface (44) of the implant. Both the staple and implant include a surface that could hold a graft should it be desired. When inserted, the staple will inhibit rotation of the implant while being positioned within a slot found within bone.

For the method claims, again see Column 7, Line 55 through Column 8, Line 65 but instead interpret the staple as the driver (due to the shape of its distal end). For the driver, use the pre-boring tool or the boring tool in order to form the slot of claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs, et al in view of Michelson (US Patent 6,241,770).

Kohrs, et al discloses all of the claimed limitations except for the implant being made of a resorbable material. Michelson teaches (Column 2, Lines 8-20) that implants for spinal surgery can use resorbable materials in order to promote fusion and bone

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growth. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implants of Kohrs, et al out of a resorbable material to enhance fusion and bone growth.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs, et al in view of Bressman, et al (US Patent 5,620,323).

Kohrs, et al disclose all of the claimed limitations except for using a self-tapping bone screw in order to simultaneously drive and form the aperture that the implant will be seated. Bressman, et al teaches the use of a self-tapping screw (Column 3, Lines 55-57) because it avoids the need to tap threads and thus reduces surgical time and complexity. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Kohrs, et al to utilize a self-tapping bone screw to simultaneously drive and form the aperture in bone in order to reduce surgical time and complexity.

Allowable Subject Matter

Claims 9-12, 22, 23, 26 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday during (7am-5pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard Shaffer
January 17th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER